Docket No. BPH-1 Applicant: Koleng et al. Filing Date: 4/2/2004

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CLAIMS

- 1. A rapidly dissolving solid oral compressed composition comprising:
 - a. one or more magnesium salts;
 - b. one or more hydrophilic polymers;
- 5 c. one or more disintegrants;
 - d. optionally one or more surfactants;
 - e. optionally one or more glidants;
 - f. optionally one or more fillers; and
 - g. optionally one or more lubricants;
- h. wherein the composition provides a substantially stable dissolution profile when evaluated in vitro according to USP <711> for the one or more magnesium salts when the composition is stored for at least two months at 40°C and 75% relative humidity in a sealed container-enclosure system.
- 2. The composition of claim 1, wherein the magnesium salt is MgO, Mg Carbonate, MgF₂, or Mg(OH)₂.
 - 3. The composition of claim 1, wherein the one or more hydrophilic polymers is a combination of polymers.
 - 4. The composition of claim 3, wherein the one or more hydrophilic polymers is selected from the group consisting of polyethylene glycol, poloxamer, povidone, and co-povidone.
- 5. The composition of claim 1, wherein the disintegrant is selected from the group consisting of: crospovidone, low substituted hydroxypropylcellulose, croscarmellose sodium, and sodium starch glycolate.
 - 6. The composition of claim 1 further comprising a coating surrounding the compressed composition.
- 7. The composition of claim 1, wherein the composition is included in a tablet or capsule dosage form
 - 8. The composition of claim 1, wherein the composition is prepared by dry granulation.

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- 9. The composition of claim 1, wherein the composition is prepared by direct compression.
- 10. The composition of claim 1, wherein the magnesium salt is a sparingly soluble, slightly soluble, very slightly soluble, practically insoluble or insoluble salt.
- 11. The composition of claim 1, wherein the magnesium salt is the only component present in a therapeutically effective amount.
 - 12. The composition of claim 1 further comprising a capsule shell within which the compressed composition is enclosed.
 - 13. The composition of claim 1, wherein the compressed composition is tablet or pill.
- 14. The composition of claim 13, wherein the tablet or pill exhibits a hardness of about 4 kp to about 50 kp.
 - 15. The composition of claim 1, wherein the dissolution medium for evaluation is dilute hydrochloric acid.
 - 16. The composition of claim 1, wherein the solid oral compressed composition is in a sealed container-enclosure system during storage.
- 15 17. The composition of claim 16, wherein
 - a. the container comprises a material selected from the group consisting of glass, metal, or polymers;
 - b. the enclosure comprises a material selected from the group consisting of metal or polymers; and
- c. the container-enclosure system is sealed by mechanical tightening and induction sealing of a taper evident liner onto the orifice of the container.
 - 18. The composition of claim 17, wherein
 - a. the container comprises high density polyethylene;
 - b. the enclosure comprises CRC or non-CRC polypropylene; and
- c. the container-enclosure system is sealed using an appropriate torque and an induction sealed aluminum tamper evident liner.
 - 19. The composition of claim 18, wherein the compressed composition is prepared by direct compression.

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- 20. The composition of claim 1, where in the compressed composition contains less than 7.5% water.
- 21. The composition of claim 20, wherein the compressed composition contains less than 5.5% water.
- 5 22. The composition of claim 21, wherein the compressed composition contains less than 4% water.
 - 23. A solid oral dosage form comprising:
 - a. a compressed composition comprising:
 - i. one or more magnesium salts;
- ii. one or more hydrophilic polymers;
 - iii. one or more disintegrants;
 - iv. optionally one or more surfactants;
 - v. optionally one or more glidants;
 - vi. optionally one or more fillers; and
- vii. optionally one or more lubricants; wherein
 - viii. the composition provides a substantially stable dissolution profile when evaluated in vitro according to USP <711> for the one or more magnesium salts when the composition is stored for at least two months at 40°C and 75% relative humidity in a sealed container-enclosure system.
- 24. The dosage form of claim 23, wherein the magnesium salt is the only component present in a therapeutically effective amount.
 - 25. The dosage form of claim 23, wherein the magnesium salt is a sparingly soluble, slightly soluble, very slightly soluble, practically insoluble or insoluble salt.
- 26. The dosage form of claim 25, wherein the magnesium salt is selected from the group consisting of MgO, Mg(OH)₂, MgF₂, and Mg Carbonate.
 - 27. The dosage form of claim 25, wherein the one or more hydrophilic polymers is a combination of polymers.
 - 28. The dosage form of claim 23, wherein the one or more hydrophilic polymers is a combination of polymers.

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- 29. The dosage form of claim 23, wherein the composition is prepared by dry granulation.
- 30. The dosage form of claim 23, wherein the composition is prepared by direct compression.
- 31. The dosage form of claim 23, wherein the composition contains less than 7.5% water.
- 32. The dosage form of claim 31, wherein the composition is prepared by dry granulation.
- 5 33. The dosage form of claim 31, wherein the composition is prepared by direct compression.
 - 34. The dosage form of claim 23 further comprising a coating surrounding the compressed composition.
 - 35. The dosage form of claim 23 further comprising a capsule shell within which the compressed composition is enclosed.
- 10 36. A compressed composition adapted for oral administration to a subject comprising:
 - a. one or more magnesium salts;
 - b. one or more hydrophilic polymers;
 - c. one or more disintegrants;
 - d. optionally one or more surfactants;
- e. optionally one or more glidants;

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- f. optionally one or more fillers; and
- g. optionally one or more lubricants; wherein
- h. the magnesium salt is the only component present in a therapeutically effective amount;
- i. the composition provides a substantially stable dissolution profile when evaluated in vitro according to USP <711> for the one or more magnesium salts when the composition is stored for at least two months at 40°C and 75% relative humidity in a sealed containerenclosure system; and
- j. the composition contains less than 7.5% water.
- 37. The composition of claim 36, wherein the magnesium salt is a sparingly soluble, slightly soluble, very slightly soluble, practically insoluble or insoluble salt.
 - 38. The composition of claim 37, wherein the magnesium salt is selected from the group consisting of MgO, Mg(OH)₂, MgF₂, and Mg Carbonate.

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- 39. The composition of claim 37, wherein the composition is prepared by direct compression or dry granulation.
- 40. The composition of claim 36, wherein the composition is prepared by direct compression or dry granulation.
- 5 41. The composition of claim 36, wherein the composition is prepared by a process that does not include the addition of water.
 - 42. The composition of claim 36, wherein
 - a. the container comprises a material selected from the group consisting of glass, metal, or polymers;
- b. the enclosure comprises a material selected from the group consisting of metal or polymers; and
 - c. the container-enclosure system is sealed by mechanical tightening and induction sealing of a taper evident liner onto the orifice of the container.
 - 43. The composition of claim 36, wherein the composition excludes microcrystalline cellulose.
- 15 44. A rapidly dissolving solid oral compressed composition comprising:
 - a. one or more magnesium salts;
 - b. one or more hydrophilic polymers;
 - c. one or more disintegrants; and
 - d. at least one or more of the following: surfactant, glidant, filler, and lubricant; wherein
- e. the composition provides a substantially stable dissolution profile when evaluated in vitro according to USP <711> for the one or more magnesium salts when the composition is stored for at least two months at 40°C and 75% relative humidity in a sealed container-enclosure system;
 - f. the composition is prepared by a substantially anhydrous process; and
- g. the magnesium salt is a sparingly soluble, slightly soluble, very slightly soluble, practically insoluble or insoluble salt.
 - 45. The composition of claim 44, wherein the magnesium salt is selected from the group consisting of MgO, Mg(OH)₂, MgF₂, and Mg Carbonate.
- 46. The composition of claim 44, wherein the composition is prepared by direct compression or dry granulation.

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- 47. The composition of claim 44, wherein the composition contains less than 7.5% water.
- 48. The dosage form of claim 44, wherein the one or more hydrophilic polymers is a combination of polymers.
- 49. The composition of claim 44, wherein the magnesium salt is the only component present in a therapeutically effective amount.
 - 50. The composition of claim 44, wherein the one or more hydrophilic polymers is selected from the group consisting of polyethylene glycol, poloxamer, povidone, and co-povidone.
- 51. The composition of claim 44, wherein the disintegrant is selected from the group consisting of: crospovidone, low substituted hydroxypropylcellulose, croscarmellose sodium, and sodium starch glycolate.
 - 52. A rapidly dissolving solid oral compressed composition comprising:
 - a. one or more magnesium salts selected from the group consisting of MgO, Mg(OH)₂, MgF₂, and Mg Carbonate;
 - b. one or more hydrophilic polymers;
- 15 c. one or more disintegrants; and
 - d. at least one or more of the following: surfactant, glidant, filler, and lubricant; wherein
 - e. the composition provides a substantially stable dissolution profile when evaluated in vitro according to USP <711> for the one or more magnesium salts when the composition is stored for at least two months at 40°C and 75% relative humidity in a sealed container-enclosure system;
 - f. the composition is prepared by a substantially anhydrous process;
 - g. the magnesium salt is a sparingly soluble, slightly soluble, very slightly soluble, practically insoluble or insoluble salt; and
 - h. the magnesium salt is the only component present in a therapeutically effective amount.
- 25 53. The composition of claim 52, wherein the composition is prepared by direct compression or dry granulation.
 - 54. The composition of claim 52, wherein the composition contains less than 7.5% water.
 - 55. The dosage form of claim 52, wherein the one or more hydrophilic polymers is a combination of polymers.

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56. The composition of claim 55, wherein the one or more hydrophilic polymers is selected from the group consisting of polyethylene glycol, poloxamer, povidone, and co-povidone.

- 57. The composition of claim 52, wherein the disintegrant is selected from the group consisting of: crospovidone, low substituted hydroxypropylcellulose, croscarmellose sodium, and sodium starch glycolate.
- 58. The composition of claim 52, wherein the composition excludes microcrystalline cellulose.